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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/583,890                       | 06/22/2006  | Albert Schaap        | 4662-196            | 1731             |
| 23117                            | 7590        | 06/11/2009           | EXAMINER            |                  |
| NIXON & VANDERHYE, PC            |             |                      | BADR, HAMID R       |                  |
| 901 NORTH GLEBE ROAD, 11TH FLOOR |             |                      |                     |                  |
| ARLINGTON, VA 22203              |             |                      | ART UNIT            | PAPER NUMBER     |
|                                  |             |                      | 1794                |                  |
|                                  |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                  |             |                      | 06/11/2009          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/583,890             | SCHAAP ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | HAMID R. BADR          | 1794                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-26 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____ .                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/22/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: ____ .                         |

## DETAILED ACTION

### ***Claim Objections***

1. Claim 20 is objected to for "POV" and "AnV". POV should be spelled out as "Peroxide Value" and AnV should be written as "Anisidine Value". Correction is required.
2. Claim 6 is objected to for "PTFE". The chemical name of the polymer should be spelled out to avoid any confusion as to what is encompassed by the claim. Correction is required.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 6-7, 11, 13-16, 17, 19, 22, 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 6 is indefinite for section f, and h for phrases: "for example by using a filter" and "for example PTFE", "for example using an oxygen scavenger" "for example sodium sulphite or hydrazine". Regarding claim6, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
4. Claim 6 is indefinite for section g for "inert gas such as nitrogen", "a noble gas such as helium or steam" and for section b "such as in a centrifuge or a cyclone".  
Regarding claim 6 section b and g, the phrase "such as" renders the claim indefinite

because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Further, since steam is not a noble gas, it is not clear what is meant by “a noble gas such as steam”.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 section f recites the broad recitation membrane, and the claim also recites an inert polymer which is the narrower statement of the range/limitation.

6. Claim 6 is also indefinite for section a and b. Since application of vacuum is considered a mechanical deaeration technique, it is not clear why “application of vacuum” and “mechanical deaeration/degassing” have been claimed as different techniques.

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7. Claim 7 is indefinite for "and/or". It is not clear what is meant by "and/or". It is not clear if "reduced stirring" or "gas displacement" or both of these limitations are required.

8. The following claims are also indefinite for broad range/narrow range limitations.

Claim 11 for " broad range 800 mbara –narrow range 600 mbara", Claim 13 for "broad 20 ppm-narrow 10 ppm", Claim 14 for "broad 10 ppm-narrow 5ppm, 2 ppm", Claim 15 for "broad above bara-narrow above 2 bara" and also for "broad above 60C -narrow above 100C", Claim 16 for "broad above 80C-narrow above 100C", Claim 26 for "broad 800 mbara-narrow 600 mbara".

9. Claims 17, 20 and 24 are indefinite for "and/or". It is not clear what is meant by "and/or".

Claims 19 and 22 are indefinite for "microbial or single cell oil". Since microbial and single cell can imply the same entity, it is not clear what is meant by microbial or single cell. If a multi-cellular organism (e.g. filamentous fungi) is meant versus a single cell (e.g. yeast) organism, the phrase should be clarified.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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11. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bijl et al. (WO 97/37032; hereinafter R1) in view of Baugh et al. (US 4,970,167; hereinafter R2).

12. R1 discloses a method for the recovery of microbial polyunsaturated fatty acid (PUFA)-containing oil. The oil is recovered from a microbial biomass after pasteurizing the fermentation broth. (Abstract)

13. R1 discloses that the oil is obtained from a microbial biomass. (page 3, paragraph 1).

14. R1 discloses that the process for obtaining the oil of the invention may remove one or more oxidative or oxidation-causing substances that may have been originally present in the biomass. (page 3, paragraph 4). R1 further discloses that the process can involve the formation of a granular particulate form which may render the PUFA less accessible to atmospheric oxygen, thereby reducing the chances of oxidation. (page 3, paragraph 6)

15. The deaeration techniques of claim 6, a-i, are all known techniques in the art. For instance chemical deaeration by sodium sulphite or hydrazine is well known. Gas displacement techniques using nitrogen are well known. Application of vacuum and stirring under vacuum are all known techniques.

16. R1 discloses that the oil may contain radical inhibitors, radical scavengers or antioxidants (page 3 last paragraph to page 4 line 1).

17. R1 discloses that the polyunsaturated fatty acid can be C18, C20, C22 omega 3 and C18, C20 or C22 omega 6 or a C20 omega 6 PUFA as presently claimed. These

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PUFAs include arachidonic acid (ARA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) (page 4, paragraph 1). It also contains gamma linolenic acid (GLA) (page 5, lines 30-34).

18. R1 discloses that the anisidine value of the PUFA containing oil is 0.1-2. (page 5, lines 20-21). Example 23 (page 49-50) shows the results of peroxide value and anisidine value of the extracted oils. Peroxide value of the extracted oil is below 12 and anisidine value is below 20 as presently claimed in claim 20.

19. R1 discloses that the PUFA containing oil can originate from any organism which can produce PUFAs including bacteria, yeast, fungi, algae or a mixture thereof. (page 5, lines 1-2).

20. R1 discloses the process for the isolation of one or more compounds from the microbial biomass comprising: culturing the microorganisms in a fermentation broth whereby the compound is produced, pasteurizing the fermentation broth or the microbial biomass derived from the broth and extracting, isolating or recovering the compound from the microbial biomass. (page 7, first paragraph).

21. R1 discloses that the fermentation broth can be filtered. (page 8, lines 15-16)

22. R1 discloses that for thermally stable products processing at higher temperatures e.g. 60C-100C may be applied. R1 teaches of pasteurizing the fermentation broth at temperatures from 60C to 100C (page 15, line13-15). R1 also discloses various methods for extracting and obtaining the oil including solvent extraction using hexane (page 31, paragraph 2 and page 29, step i).

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23. While R1 discloses that the process can involve the formation of a granular particulate form which may render the PUFA less accessible to atmospheric oxygen, thereby reducing the chances of oxidation, R1 is silent regarding deaerating an aqueous liquid comprising cells.

24. R2 discloses a post fermentation degassing technique. (Abstract). R1 discloses a sequential fermentation and degassing of fermentation broths. (Col. 2, lines 34-40).

25. R2 discloses means for culturing or fermentation of microbial cells (Col. 6, Fermentation). R2 also discloses means for degassing (degassification ) of a fermentation broth (Col. 10, Degassification) including degassing nozzles (Col. 3, lines 15-40). R2 discloses that the vapor space in the degassification chamber can be maintained at atmospheric, sub-atmospheric or super atmospheric pressure. Given that the chamber can be operated at sub-atmospheric pressures (vacuum operated), the deaerator of claim 23-24 will be obvious to those of skill in the art. The vacuum pressures can also be optimized so that the concentration of dissolved oxygen can be lowered to levels including those concentrations as presently claimed in claims 13-14. Given that sub-atmospheric pressures as well as nozzles in the degassing chamber are disclosed by R2, the vacuum, degassing pump or nozzle of claim 25 will be also obvious to those of skill in the art.

26. R2 discloses that the degassed fermentation broth can be pasteurized (Col. 4, lines35-39). Given that pasteurization can be carried out after the degassing process, claim 3 would be obvious to those of skill in the art.

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27. Given the disclosure by R2 regarding the operation of the degassing chamber under vacuum, the limitations of claim 26 which are equivalent to -200 mbar to -400 mbar vacuum are operational vacuums and can be optimized by those of skill in the art. Since under standard pressure and temperature (1 atm pressure and 25C) the solubility of oxygen in water is about 8 ppm, lowering the pressure will cause a decrease in the concentration of dissolved oxygen. Therefore, an artisan would reduce the pressure to a level where the solubility of oxygen is decreased to a point so that PUFA will no longer be oxidized at a accelerated rate.

28. Given the disclosures of R1 and R2 regarding the processing of microbial cells, the limitations of section c of claim 24 for a homogenizer and centrifuge are also known and standard equipment in the art. A homogenizer is used to break down the microbial cells so that that oil is expelled from the microbial cells. Centrifuging a liquid containing oil will cause the separation of oil from the aqueous medium and cell debris.

29. Since R1 discloses the sensitivity of polyunsaturated fatty acids to oxidation by atmospheric oxygen and remedies the problem through certain means, it is obvious that those of skill in the art are motivated to use other means of deaerating the fermentation broth to protect the sensitive polyunsaturated fatty acids. Therefore, it would have been obvious to one ordinary skill in the art, at the time the invention was made, to grow PUFA containing cells in a fermentation process as taught by R1 and exclude oxygen from the fermentation broth as taught by R2, or other techniques known in the art, to protect the highly unsaturated fatty acids from oxidation. One would do so to obtain microbial oils which are nutritionally and organoleptically of high quality. Absent any

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evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in preparing microbial oils containing PUFA of high quality.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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